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**CHINA MEDICAL SYSTEM HOLDINGS LIMITED**  
**康哲藥業控股有限公司\***

*(Incorporated in the Cayman Islands with limited liability)*

**(Stock Code: 867)**

**INTERIM RESULTS ANNOUNCEMENT**  
**FOR THE SIX MONTHS ENDED 30 JUNE, 2020**

The Board of Directors (the “Board”) of China Medical System Holdings Limited (the “Company”) is pleased to announce the unaudited condensed consolidated results of the Company and its subsidiaries (the “Group” or “CMS”) for the six months ended 30 June 2020 (the “Reporting Period”).

**Financial Highlights**

- Turnover up 4.8% to RMB3,108.1 million (H1 2019: RMB2,964.4 million); excluding the effect of the “two-invoice system”, turnover up 4.6% to RMB3,557.1 million (H1 2019: RMB3,401.5 million)
- Gross profit up 3.4% to RMB2,293.4 million (H1 2019: RMB2,217.5 million); excluding the effect of the “two-invoice system”, gross profit up 6.8% to RMB2,161.7 million (H1 2019: RMB2,023.2 million)
- Profit for the period up 11.4% to RMB1,300.5 million (H1 2019: RMB1,167.5 million)
- Basic earnings per share up 9.7% to RMB0.5174 (H1 2019: RMB0.4717)
- As at 30 June 2020, the Group’s bank balances and cash amounted to RMB2,109.1 million while readily realizable bank acceptance bills amounted to RMB315.6 million
- Declared interim dividend up 11.8% compared with the same period last year to RMB0.2105 per share (H1 2019: RMB0.1883)

## **Business Highlights**

During the Reporting Period, the Group made significant progress in the expansion of the innovative pipeline as well as the registration and clinical work of innovative products, summarized as follows:

### ***The Innovative Pipeline Continued to Expand***

- Acquired the exclusive license of the innovative product PLENITY® in Mainland China, HK SAR, Macau SAR, TWN, Singapore and the United Arab Emirates. PLENITY® is a U.S. FDA-cleared, safe and effective orally-administered weight management product made from naturally derived materials.
- Acquired the exclusive license of the innovative product Desidustat in Mainland China, HK SAR, Macau SAR and TWN. Desidustat is a patented new molecular entity for the treatment of anemia in patients with chronic kidney disease.

### ***The Registration and Clinical Work of Innovative Products in China Attained Positive Progress***

- Related work for the comparative PK study of the innovative product Diazepam Nasal Spray in healthy subjects has been carried out, and the ethical approval for this study was obtained from the research center.
- The innovative product Cyclosporine Eye Drops 0.09% has been granted a clinical trial notice issued by China NMPA, which agreed to a randomized, double-blind, placebo-controlled, multi-center clinical study on the safety and effectiveness of the product for the treatment of keratoconjunctivitis sicca.
- The clinical trial application of the innovative product Tildrakizumab has been accepted by China NMPA.

### ***The Existing Businesses Achieved Steady Development***

- Recorded solid growth across core product lines.
- The operation efficiency of the professional, compliant and efficient promotion system has been further improved through digitalization; and the expansion and refinement of the promotion network continued. During the Reporting Period, the Group's promotion network covered about 57,000 hospitals and medical institutions in China.

CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER  
 COMPREHENSIVE INCOME  
 FOR THE SIX MONTHS ENDED 30 JUNE 2020

	NOTES	Six months ended 30 June	
		2020	2019
		RMB'000	RMB'000
		(unaudited)	(unaudited)
Turnover	3	3,108,075	2,964,360
Cost of goods sold		(814,670)	(746,881)
Gross profit		2,293,405	2,217,479
Other gains and losses		63,285	46,673
Selling expenses		(825,572)	(881,375)
Administrative expenses		(98,985)	(96,497)
Research and development expenses		(30,352)	(15,435)
Finance costs		(15,344)	(29,065)
Share of results of associates		80,963	56,773
Profit before tax		1,467,400	1,298,553
Income tax expense	4	(166,885)	(131,033)
Profit for the period	5	1,300,515	1,167,520
<i>Items that may be reclassified subsequently to profit or loss:</i>			
Share of other comprehensive income of associates		8,612	780
Exchange differences arising from translation of foreign operations		(1,090)	(987)
Change in fair value on cash flow hedges			
- fair value loss		(7,905)	(14,368)
- deferred tax relating to change in fair value		1,304	2,371
<i>Item that will not be reclassified to profit or loss:</i>			
Fair value (loss) gain on equity instrument at fair value through other comprehensive income		(18,159)	15,101
Other comprehensive (expense) income for the period, net of income tax		(17,238)	2,897
Total comprehensive income for the period		1,283,277	1,170,417
Profit (loss) for the period attributable to:			
Owners of the Company		1,279,421	1,169,896
Non-controlling interests		21,094	(2,376)
		1,300,515	1,167,520
Total comprehensive income (expense) for the period attributable to:			
Owners of the Company		1,262,183	1,172,793
Non-controlling interests		21,094	(2,376)
		1,283,277	1,170,417
		RMB	RMB
Earnings per share	7		
Basic		0.5174	0.4717

CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION  
AT 30 JUNE 2020

	<u>NOTES</u>	30 June <u>2020</u> RMB'000 (unaudited)	31 December <u>2019</u> RMB'000 (audited)
<b>Non-current assets</b>			
Property, plant and equipment		474,939	472,901
Right-of-use assets		60,316	64,986
Interest in associates		2,609,609	2,590,159
Intangible assets		2,378,157	2,459,128
Goodwill		1,384,535	1,384,535
Equity instruments at fair value through other comprehensive income		394,177	269,704
Deposits paid for acquisition of intangible assets		518,044	325,126
Amount due from an associate	9	31,816	31,816
Derivative financial instruments		21,432	-
Deferred tax assets		20,408	20,298
		<u>7,893,433</u>	<u>7,618,653</u>
<b>Current assets</b>			
Inventories		430,270	407,058
Financial asset at fair value through profit or loss		2,736	2,736
Trade and other receivables	8	1,452,621	1,585,724
Tax recoverable		12,842	10,801
Derivative financial instruments		733	28,192
Amount due from an associate	9	127,727	152,804
Bank balances and cash		2,109,075	1,365,008
		<u>4,136,004</u>	<u>3,552,323</u>
<b>Current liabilities</b>			
Trade and other payables	10	290,264	372,796
Lease liabilities		7,378	9,388
Contract liabilities		8,468	12,939
Bank borrowings		48,831	693,909
Derivative financial instruments		-	142
Deferred consideration payables		2,929	10,744
Tax payable		526,311	447,784
		<u>884,181</u>	<u>1,547,702</u>
Net current assets		<u>3,251,823</u>	<u>2,004,621</u>
Total assets less current liabilities		<u>11,145,256</u>	<u>9,623,274</u>

	30 June <u>2020</u> RMB'000 (unaudited)	31 December <u>2019</u> RMB'000 (audited)
Capital and reserves		
Share capital	84,634	84,963
Reserves	<u>10,249,412</u>	<u>9,387,898</u>
Equity attributable to owners of the Company	10,334,046	9,472,861
Non-controlling interests	<u>64,365</u>	<u>43,271</u>
	<u>10,398,411</u>	<u>9,516,132</u>
Non-current liabilities		
Bank borrowings	637,155	-
Deferred tax liabilities	88,961	91,552
Lease liabilities	8,451	10,491
Derivative financial instruments	8,047	-
Deferred consideration payables	<u>4,231</u>	<u>5,099</u>
	<u>746,845</u>	<u>107,142</u>
	<u>11,145,256</u>	<u>9,623,274</u>

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NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE SIX MONTHS ENDED 30 JUNE 2020

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1. BASIS OF PREPARATION

The condensed consolidated financial statements have been prepared in accordance with International Accounting Standard 34 *Interim Financial Reporting* issued by the International Accounting Standards Board (“IASB”) as well as with the applicable disclosure requirements of Appendix 16 to the Rules Governing the Listing of Securities on the Stock Exchange of Hong Kong Limited (the “SEHK”) (the “Listing Rules”).

2. PRINCIPAL ACCOUNTING POLICIES

The condensed consolidated financial statements have been prepared on the historical cost basis except for certain financial instruments, which are measured at fair values, as appropriate.

Except as described below, the accounting policies and methods of computation used in the condensed consolidated financial statements for the six months ended 30 June 2020 are the same as those followed in the preparation of the Group’s annual financial statements for the year ended 31 December 2019.

In the current interim period, the Group has applied, for the first time, certain new or revised International Financial Reporting Standards (“IFRSs”) issued by the IASB that are mandatorily effective for the current interim period. The application of new or revised IFRSs in the current interim period has had no material effect on the amounts reported in these condensed consolidated financial statements and/or disclosures set out in these condensed consolidated financial statements.

### 3. TURNOVER AND SEGMENT INFORMATION

The Group sells and promotes pharmaceutical products to hospital and medical institutions throughout the People's Republic of China (the "PRC" or "China") through academic promotion network and agency promotion network.

For sales of pharmaceutical products to customers, revenue is recognised at a point in time when control of the pharmaceutical products is passed to customers, i.e. when the products are delivered and titles have passed to customers upon receipt by customers. For provision of promotion services to customers, revenue is recognised at a point in time when the Group satisfies its obligation to arrange for the pharmaceutical products to be provided by suppliers to distributors.

The following is an analysis of the Group's revenue from its major products and services:

	<u>Six months ended 30 June</u>	
	<u>2020</u>	<u>2019</u>
	RMB'000	RMB'000
Sales of pharmaceutical products	2,537,816	2,290,560
Promotion income	570,259	673,800
	<u>3,108,075</u>	<u>2,964,360</u>

The Group determines its operating segments based on the internal reports reviewed by the chief operating decision maker, the Executive Directors of the Company that are used for resources allocation and assessment of segment performance.

The Group only has one reportable operating segment that is marketing, promotion, sales and manufacturing of pharmaceutical products. No operating results and discrete financial information is available for the assessment of performance of the respective business divisions and resources allocation purpose.

No analysis of the Group's assets and liabilities by operating segments is disclosed and provided to the chief operating decision maker for review as the Group only has one reportable operating segment.

The implementation of sale and promotion of the Group primarily takes place in the PRC. Almost all revenue from external customers is attributed to the PRC and the majority of fixed assets of the Group are located in the PRC.

4. INCOME TAX EXPENSE

	<u>Six months ended 30 June</u>	
	<u>2020</u>	<u>2019</u>
	RMB'000	RMB'000
Current tax:		
PRC Enterprise Income Tax	114,350	114,599
Hong Kong Profits Tax	180	1,736
Malaysia Corporate Income Tax	-	20,495
Macau Complementary Income Tax	53,752	-
	<u>168,282</u>	<u>136,830</u>
Deferred taxation:		
Current period	(1,397)	(5,797)
Income tax expense for the period	<u>166,885</u>	<u>131,033</u>

Note: As disclosed in the Company's annual report 2019, the applicable income tax rate (3% or 24%) of the Group's former subsidiary CMS Pharma Co., Ltd for the year ended 31 December 2019 is still to be approved by the Malaysia government. As at the date that the condensed consolidated financial statements were approved for issue, pursuant to the circular on extension of income tax filing issued by the Malaysia tax authority, CMS Pharma Co., Ltd has not yet completed its income tax filing and payment for the year ended 31 December 2019, therefore the related income tax provision remained.

5. PROFIT FOR THE PERIOD

	<u>Six months ended 30 June</u>	
	<u>2020</u>	<u>2019</u>
	RMB'000	RMB'000
Profit for the period has been arrived at after charging (crediting):		
Depreciation of property, plant and equipment	18,805	17,311
Amortisation of intangible assets (included in cost of goods sold)	80,971	81,158
Cost of inventories recognised as an expense	728,655	660,082
Interest income	(26,044)	(17,521)
Net exchange gain	<u>(4,758)</u>	<u>(4,280)</u>

## 6. DIVIDENDS

During the Reporting Period, a final dividend of RMB0.1271 per share in respect of the year ended 31 December 2019 (six months ended 30 June 2019: RMB0.1434 per share in respect of the year ended 31 December 2018) was declared and paid to the owners of the Company. The aggregate amount of the final dividend declared and paid during the Reporting Period amounted to RMB314,034,000 (six months ended 30 June 2019: RMB355,691,000).

Subsequent to the end of the interim period, the Directors have determined that an interim dividend of RMB0.2105 per share and amounting to RMB520,095,000 (six months ended 30 June 2019: RMB0.1883 per share and amounting to RMB467,061,000) will be paid to the owners of the Company whose names appear in the Register of Members on 28 August 2020.

## 7. EARNINGS PER SHARE

The calculation of the basic earnings per share attributable to the owners of the Company is based on the following data:

	<u>Six months ended 30 June</u>	
	<u>2020</u>	<u>2019</u>
	RMB'000	RMB'000
Earnings for the purposes of basic earnings per share (profit for the period attributable to owners of the Company)	<u>1,279,421</u>	<u>1,169,896</u>
	Number of ordinary shares	
	<u>As at 30 June</u>	
	<u>2020</u>	<u>2019</u>
Weighted average number of ordinary shares for the purpose of basic earnings per share	<u>2,472,986,974</u>	<u>2,480,408,512</u>

The Group has no outstanding potential ordinary shares as at 30 June 2020 and 2019 and during the periods ended 30 June 2020 and 2019. Therefore, no diluted earnings per share is presented.

8. TRADE AND OTHER RECEIVABLES

	30 June <u>2020</u> RMB'000	31 December <u>2019</u> RMB'000
Trade receivables	936,476	1,010,198
Less: Allowance for credit losses	<u>(8,336)</u>	<u>(8,336)</u>
	928,140	1,001,862
Bills receivables	315,622	414,017
Purchase prepayment	165,528	73,039
Other receivables and deposits	<u>43,331</u>	<u>96,806</u>
	<u>1,452,621</u>	<u>1,585,724</u>

The Group normally allows a credit period ranging from 0 to 90 days to its trade customers, but longer credit period up to four months is allowed to some selected customers.

An aging analysis of the trade receivables (net of allowance for credit losses) presented based on the invoice date at the respective reporting dates, which approximated the respective revenue recognition date, is as follows:

	30 June <u>2020</u> RMB'000	31 December <u>2019</u> RMB'000
0 - 90 days	913,085	923,722
91 - 365 days	<u>15,055</u>	<u>78,140</u>
	<u>928,140</u>	<u>1,001,862</u>

The bills receivables of the Group are of the age within six months at the end of the Reporting Period.

The Group applies the IFRS 9 simplified approach to measure expected credit loss (“ECL”) which uses a lifetime ECL, trade receivables have been grouped based on shared credit risk characteristics and the historical observed default rates adjusted by forward-looking estimates. As at 30 June 2020, the majority balances of trade receivables were within the credit period, the Directors of the Company considered that the lifetime ECL allowance is insignificant as at 30 June 2020.

#### 9. AMOUNT DUE FROM AN ASSOCIATE

As at 30 June 2020, the balance of approximately RMB31,816,000 (31 December 2019: RMB31,816,000) represented deposit to Tibet Rhodiola Pharmaceutical Holding Co. (“Tibet Pharmaceutical”) for exclusive distribution right.

As at 30 June 2020, the balance of approximately RMB127,727,000 (31 December 2019: RMB152,804,000) represented promotion income receivables from Tibet Pharmaceutical. The Group allows a credit period of 90 days to Tibet Pharmaceutical. The balance as at 30 June 2020 was aged within three months (31 December 2019: within three months) based on the invoice date.

## 10. TRADE AND OTHER PAYABLES

An aging analysis of the trade payables presented based on the invoice date at the end of the Reporting Period is as follows:

	30 June <u>2020</u> RMB'000	31 December <u>2019</u> RMB'000
0 - 90 days	76,947	37,941
91 - 365 days	3,092	4,762
Over 365 days	<u>1,338</u>	<u>1,337</u>
Trade payables	81,377	44,040
Payroll and welfare payables	90,008	124,873
Other tax payables	17,310	67,186
Accrued promotion expenses	61,463	85,555
Accruals	19,864	31,746
Other payables	<u>20,242</u>	<u>19,396</u>
	<u>290,264</u>	<u>372,796</u>

The credit period on purchases of goods ranges from 0 to 120 days.

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# Management Discussion and Analysis

## Overview

CMS is a well-established, innovation-driven specialty pharma with a focus on sales and marketing in China. The Group concentrates on the innovative products that are global first-in-class or with the best efficacy or best cost-effectiveness in the same class due to their innovative formulations or drug delivery systems. Capitalizing on its resources of global product development accumulated for more than two decades, as well as the market reputation earned, the Group has established strategic cooperation relationships with a number of leading pharmaceutical companies around the world and made equity investments in innovative research and development (“R&D”) companies from the U.K., France, the U.S. and Switzerland. The Group’s innovative pipeline includes products with great market potential and competitive differentiation advantages at relatively high innovation level, covering various therapeutic fields including nervous system, ophthalmology, dermatology, endocrine system, oncology, nephrology, immune system, digestive system, anti-infection, etc. As at 30 June 2020, the Group owned 20 innovative products, among them, 6 products have been approved for marketing by the U.S. Food and Drug Administration (“FDA”) and 2 under the review for marketing approval by the U.S. FDA; 2 innovative products have been granted clinical trial notices issued by the National Medical Products Administration (“NMPA”) of China for comparative pharmacokinetics study (“PK study”) and confirmatory clinical trial respectively, and the application for confirmatory clinical trial of 1 innovative product has been accepted by China NMPA.

With its proven and successful experience in drug promotion for over two decades, the Group has created good sales records for a number of quality branded drugs and received high recognition from its partners. The Group focuses on exploring the evidence-based medical evidence and differentiation competitive advantages of the drugs and has established a professional, compliant and efficient academic promotion system. Combined with its timely, refined, transparent and efficient internal management system, the Group has become one of the most efficient companies in China pharmaceutical industry.

## Business Review

During the Reporting Period, with the normalization of the National Volume-based Procurement, the intensification of anti-corruption in the pharmaceutical industry, the issuance of Interim Administrative Measures for Basic Drugs of National Reimbursement Drug List (“NRDL”) (Draft for Soliciting Opinions), and the re-initiation of the Registration Regulation on Pharmaceutical Representatives, etc., China pharmaceutical reform has continued to deepen and progress at an accelerated pace. Facing the deepened pharmaceutical reform, the Group rose to the challenge and achieved steady and good growth with three driving forces: product competence, promotion capability and efficient management system.

## I. Product Pipeline

Sustainable product competence is the key competitive factor for future development of enterprises. Adhering to the development strategy with innovative products as the core, the Group constantly expanded the innovative pipeline, while accelerating the registration progress of innovative products in China, so as to fulfill the unmet medical needs in China pharmaceutical market. Meanwhile, the Group deployed complex generics and competitive generics to provide additional driving forces for the future development of the Group.

### 1. Continuous Expansion of Innovative Pipeline

#### **Equity Investment in Gelesis and In-licensing of the Innovative Product PLENITY® – A Safe and Effective Orally-administered Weight Management Product Made from Naturally Derived Materials**

In June 2020, the Group made an equity investment in Gelesis, Inc. (“Gelesis”), a U.S. innovative R&D company focused on a novel category of therapies for GI-related chronic diseases. Gelesis is developing a novel hydrogel platform technology, which is designed to act mechanically in the GI pathway to potentially alter the course of certain chronic diseases. As at 30 June 2020, the Group held 5.88% ownership of Gelesis.

At the same time, the Group through its wholly-owned subsidiary signed a license, collaboration and supply agreement with Gelesis for its product PLENITY® and gained an exclusive license under Gelesis intellectual property and applicable regulatory approvals to develop, import, register, make and have made, manufacture and commercialize the product in Mainland China, the Hong Kong Special Administrative Region (“HK SAR”), the Macau Special Administrative Region (“Macau SAR”), Taiwan (“TWN”), Singapore and the United Arab Emirates. The term of the agreement is 20 years from the date of signing and may be renewable for every single period of three years as per certain conditions defined in the agreement.

PLENITY®, which was approved by the U.S. FDA in April 2019, is a safe and effective orally-administered weight management product made from naturally derived materials. Used in conjunction with diet and exercise to aid for weight management in adults with a Body Mass Index (BMI) of 25–40 kg/m<sup>2</sup>, PLENITY® is a non-systemic and non-stimulant aid for weight management. After taken with water, its capsules release thousands of particles that rapidly absorb water in the stomach, creating small individual gel pieces with the elasticity and firmness of plant-based foods without caloric value. The gel contributes to a feeling of fullness and induces satiety, which can help with weight loss. The U.S. FDA approval was based on data from a randomized, double-blind, placebo-controlled pivotal clinical trial conducted on 436 patients with overweight or obesity (BMI of 27-40 kg/m<sup>2</sup>) with at least one comorbidity. After six months of treatment with PLENITY®, nearly 60% patients achieved at least 5% weight loss (an average of 10% weight loss, or 10 kg) and 26% achieved at least 10% (an average of 14% weight loss, or 13 kg). Meanwhile, PLENITY® demonstrated a highly favorable safety profile: no difference in the overall incidence of adverse events compared with placebo. In addition, PLENITY® also

received a CE mark, which allows it to be marketed in European Economic Area. PLENITY®'s core patents (namely formulation/use and preparation method patents) have been granted in Mainland China.

Statistics show that in 2015, overweight and obesity accounted for 23% and 5% of the adult population respectively in China. Currently, the commonly used weight loss and weight maintenance drugs have different degrees of adverse reactions; whilst, other products in the healthcare market have not been fully validated by evidence-based medicine in terms of effectiveness and safety. The introduction of PLENITY® would meet the market demand and provide patients with an effective and safe treatment option.

***The Innovative Product In-licensed from Zydus, Desidustat – Oral Hypoxia-inducible Factor-prolyl Hydroxylase Inhibitor (HIF-PHI)***

In January 2020, the Group through its wholly-owned subsidiary signed a license agreement with Cadila Healthcare Limited (“Zydus”) for its product Desidustat and gained a royalty-bearing, exclusive, sub-licensable license under the licensed technology and Zydus data to develop, register and to manufacture, use and commercialize the product in Mainland China, HK SAR, Macau SAR and TWN. The term of the agreement starts on the date of signing the agreement until the last date of the occurrence of the following: (i) the expiration of the last-to-expire patent containing a valid claim covering the manufacture, use, import, offer for sale or sale of the product in the related territory; (ii) ten years after the first commercial sale of the product in the related territory; and (iii) the expiration of all regulatory exclusivities for the product in the related territory. The agreement may be renewable for every single period of five years as per certain conditions defined in the agreement.

Desidustat, which is under two Phase III clinical trials overseas, is a novel oral hypoxia-inducible factor-prolyl hydroxylase inhibitor (HIF-PHI) for treating anemia in chronic kidney disease (CKD) patients. A randomized, double-blind, placebo-controlled, parallel group, multicentric Phase II clinical trial had been conducted on 117 anemia patients in non-dialysis CKD. After six weeks of treatment, as compared to placebo, in all three Desidustat arms, the therapy showed statistically significant improvement in the primary endpoint, change in the hemoglobin (Hb) from baseline, and the Hb responder rates in secondary endpoint were over 60%. In terms of safety, no serious adverse event was reported, and there was no significant change in vital signs, electrocardiographic parameters, or safety laboratory values. The Group will localize the manufacturing of the product preparations in Mainland China with technology transfer and plans to submit the Category 1 New Drug Application (“NDA”) of the product in the future. A material patent has been granted in Mainland China, HK SAR, Macau SAR and TWN concerning Desidustat, which is a new molecular entity.

It has been reported that more than 120 million people are estimated to be living with CKD in China, and anemia is one of the frequent complications of CKD. A survey in China showed that the prevalence of anemia in patients at CKD stage 1 to 5 were 22.0%, 37.0%, 45.4%, 85.1%, and 98.2%, respectively. However, the

target-achieving rate was only 8.2% for anemia patients in non-dialysis CKD and 35.2% for hemodialysis CKD, showing a large unmet treatment need. Compared with the existing therapies, Desidustat is administered orally, thus expected to improve the treatment compliance of patients.

## **2. Registration and Clinical Progress of Innovative Pipeline**

### **Diazepam Nasal Spray – An Innovative Drug Targeting Acute Repetitive Seizures That Is Convenient to Use Outside the Medical Setting and Has a Very Rapid Onset of Action**

During the Reporting Period, the related work for the comparative PK study of Diazepam Nasal Spray and diazepam injection in healthy subjects has been carried out, and the ethical approval for this study was obtained from the research center. The Group is preparing for the enrollment and related work of the study as planned, with an enrollment target of 24. In December 2019, the Group received the clinical trial notice of Diazepam Nasal Spray issued by China NMPA. The Group is required to conduct a comparative PK study in Chinese subjects, and to submit a post-marketing study plan to further verify the efficacy and safety at the same time of submitting the NDA.

In January 2020, Diazepam Nasal Spray was approved for marketing by the U.S. FDA under the VALTOCO® brand name for the treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) in patients with epilepsy six years of age and older. The product is a proprietary formulation of diazepam. Its formulation incorporates the unique combination of a vitamin E-based solvent and Intravail® absorption enhancement with the goal of obtaining unparalleled absorption, tolerability, and reliability in a nasal formulation, providing a treatment option that is easy to use outside the medical setting and has a very rapid onset of action. The U.S. FDA approval was based on data from multiple clinical trials. Compared with intravenous diazepam, PK studies in VALTOCO® in healthy subjects demonstrated 96% absolute bioavailability and comparable bioavailability to rectal diazepam gel with significantly less variability. Results of PK study in seizing patients showed similar exposure of VALTOCO® in seizing or non-seizing state/strong correlation to pharmacokinetics in healthy subjects. The 12-month open-label, long-term safety Phase III clinical trial evaluating repeated use in patients with epilepsy showed exceptional tolerability and safety of VALTOCO® in repeated at-home use during seizure conditions.

According to the estimation based on domestic epidemiological data, there are about 6 million active epilepsy patients in China, and about 0.4 million new cases reported each year. In patients with epilepsy who have received regular treatment (about 2 million), 20%-30% are still out of effective control and are at risk of repetitive seizures. Diazepam Nasal Spray will effectively fulfill the market gap and become a long-term prepared and essential medicine for patients with acute repetitive seizures.

### **Cyclosporine Eye Drops 0.09% – A Preservative-free, Innovative Ophthalmic Formulation Using Globally**

### **Patented Nanotechnology**

In April 2020, the clinical trial application of Cyclosporine Eye Drops 0.09% was accepted by China NMPA. In June, the product was granted a clinical trial notice issued by China NMPA, which agreed to a clinical trial regarding increasing tear secretion in patients with keratoconjunctivitis sicca (dry eye), namely a randomized, double-blind, placebo controlled, multi-center clinical study on the safety and effectiveness of Cyclosporine Eye Drops 0.09% for the treatment of keratoconjunctivitis sicca. During the Reporting Period, the Group successfully held an investigator meeting to discuss and confirm the details of the clinical protocol, and completed the initial screening of the research centers nationwide. The next stage of work is actively proceeding.

Cyclosporine Eye Drops 0.09% has been approved for marketing in the U.S. and Australia for increasing tear production in patients with keratoconjunctivitis sicca. Dissolved in a clear, preservative-free, aqueous solution, the product is the globally first patent-protected innovative 0.09% cyclosporine ophthalmic solution using nanotechnology. The U.S. FDA approval was based on data from a multi-center, randomized, double-blind, vehicle-controlled Phase III confirmatory study conducted on 744 patients with dry eye. After 12 weeks of treatment, as compared to vehicle, Cyclosporine Eye Drops 0.09% showed statistically significant improvement in the primary endpoint, Schirmer's score (a measurement of tear production) ( $p < 0.01$ ). Improvements in secondary endpoints (i.e. ocular staining assessments) were seen as early as 1 month after the initiating treatment.

The incidence of dry eye in China is 21%-30%, of which moderate-to-severe patients account for 40% or about 118-168 million patients. Although various symptom alleviating agents such as artificial tears are available in the market, there are few satisfactory options in practice. In addition, in terms of ophthalmic cyclosporine, related treatment options are still limited due to the historic challenge of making an optic formulation of this agent at a suitable concentration without increasing side effects. Cyclosporine Eye Drops 0.09% uses a unique tiny structure called "micelles" as a vehicle to allow for greater tissue penetration and gentle side effect profile even in a high concentration, which will greatly complement and enrich the existing therapeutic options.

### **Tildrakizumab – A Monoclonal Antibody Specifically Targeting Interleukin-23(IL-23)**

In May 2020, the clinical trial application of Tildrakizumab submitted by the Group has been accepted by China NMPA.

Tildrakizumab has been approved for marketing in the U.S., Europe and Australia for treatment of adults with moderate-to-severe plaque psoriasis that are candidates for systemic therapy or phototherapy. The U.S. FDA approval was based on data from the pivotal Phase III reSURFACE clinical development program, which consisted of two randomized, double-blind, placebo-controlled trials of more than 1,800 patients across over

200 clinical trial sites. Results from the Phase III reSURFACE 1 and 2 studies were published in The Lancet in July 2017, with primary endpoints presented at the 25th European Academy of Dermatology and Venereology (EADV) Congress. The two Phase III studies met primary efficacy endpoints, with an average of 63% of patients receiving Tildrakizumab 100 mg achieving 75% of skin clearance by week 12, and 77% of patients achieving 75% skin clearance after 28 weeks. In the meantime, a higher number of Tildrakizumab-treated patients achieved 90% and 100% of skin clearance compared with placebo and Etanercept. The substance and formulation patents of Tildrakizumab have been granted in China.

There are more than 6.5 million people suffering from psoriasis in China. About 30% of patients are with moderate-to-severe psoriasis; among them, nearly 62% are dissatisfied with existing treatment options. As a cost-effective biological agent with long-term safety and efficacy, Tildrakizumab can fulfill this unmet clinical need.

### **CF102 – A Selective Agonist to the A3 Adenosine Receptor**

In April 2020, the CF102 Phase II clinical trial for the treatment of non-alcoholic fatty liver disease (NAFLD) /non-alcoholic steatohepatitis (NASH) in Israel yielded positive line results: achieving efficacy endpoints while continuing to demonstrate a good safety profile. CF102 is a novel small molecule compound used for a second-line treatment for hepatocellular carcinoma (HCC) and a treatment for NAFLD/NASH. The product has been granted Orphan Drug Designation in the U.S. and Europe and Fast Track Designation as a second-line treatment for HCC by the U.S. FDA.

### **3. Innovative Pipeline**

As at 30 June 2020, the Group's innovative pipeline and its development process are as follows:

## Innovative Pipeline Launched Overseas (or Under Marketing Approval)

Product	Indication	Innovativeness	Clinical Trial Approval	Clinical Trial for Registration	Marketing Approval Application	Launched into the Market	Country/Region	
Diazepam Nasal Spray	6 years of age and older patient with acute repetitive seizures	Innovative drugs with proprietary technology for special dosage form						USA
								China
Cyclosporine Eye Drops 0.09%	Increasing tear production in patients with keratoconjunctivitis sicca (dry eye)	Global nanotechnology patent						USA, Australia
								China
Tildrakizumab (Biological Agent)	Moderate-to-severe plaque psoriasis	Innovative biological agent; substance patent and formulation patent						USA, Europe, Australia
								China
PLENTY (Medical Device)	Aid for weight management in adults with a BMI of 25-40 kg/m <sup>2</sup> when used in conjunction with diet and exercise	Formulation/use and preparation method patents						USA, Europe
Latanoprost Ophthalmic Emulsion	Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma, or ocular hypertension	Innovative technology platform to dissolve ophthalmic drugs with limited water absorbability						USA
Levetiracetam XR Tablet	Adjunctive therapy for the treatment of partial-onset seizures	Specialty formulation technology						USA
PoNS (Medical Device)	Chronic balance deficit due to mild-to-moderate traumatic brain injury (TBI)	Innovative medical device						Canada
								USA
Paclitaxel Injection Concentrate for Suspension	Metastatic breast cancer, locally advanced/metastatic non-small cell lung cancer, metastatic adenocarcinoma of the pancreas	Formulation patents						USA

## Innovative Pipeline Under Clinical Stages

Product	Indication	Innovativeness	Clinical Trial Approval	Phase I	Phase II	Phase III	FDA/EMA* Marketing Approval Application	Launched into the Market
CMS024	Primary liver cancer	New lead compound; substance, compound, use and application patents						
Desidustat	Anemia in chronic kidney disease (CKD) patients	New molecular entity; substance patent						
PDP-716	Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma, or ocular hypertension	Resin microparticle-complexed drug technology						
SDN-037	Eye pain and inflammation after cataract surgery	Proprietary nano-sized micelle drug delivery system						
CF101	Rheumatoid arthritis (RA)	New lead compound						
	Psoriasis							
CF102	Hepatocellular carcinoma (HCC)	New lead compound						
	Non-alcoholic fatty liver disease (NAFLD) / non-alcoholic steatohepatitis (NASH)							
XF-73	Prevention of post-surgical staphylococcal infections	New lead compound; compound patent and use patent						
BB2603	Onychomycosis and tinea pedis	Formulation patents						
ACT017 (Biological Agent)	Acute phase of ischemic stroke	Innovative biological agent; substance patent						
VXM01 (Biological Agent)	Recurrent glioblastoma (GBM)	Innovative biological agent; production process patent and use patent						

\*European Medicines Agency (“EMA”)

#### 4. List of Equity-invested R&D Companies

The Group acquires asset rights (including intellectual property rights) or obtains exclusive licensing rights (collectively, the “Product Rights”) of innovative products through equity investment and strategic cooperation. For equity investments in overseas product projects under clinical stages, to reduce risks assumed and capital spending by the Group, Mr. Lam Kong, the chairman of the Board, will typically through his privately-owned company make equity investments together with the Group on a 50:50 basis, to assist the Group in securing 100% of the Product Rights of innovative products in the relevant territories from potential R&D companies. As at 30 June 2020, the Group and/or Mr. Lam Kong (through his privately-owned company) have made equity investments in certain R&D companies, and the Group has obtained the Product Rights of their respective products which are summarized as follows:

Overseas R&D Companies	Ownership* Held by the Group	Ownership* Held by Mr. Lam Kong#	Main Products in Respect of Which the Group Acquired the Product Rights
Destiny Pharma plc.	4.36%	4.36%	XF-73
Acticor Biotech	9.32%	9.32%	ACT017
Blueberry Therapeutics Limited	14.06%	14.06%	BB2603
Neurelis, Inc.	8.92%	10.90%	Diazepam Nasal Spray
Vaximm AG	4.46%	4.46%	VXM01
Midatech Pharma PLC	13.23%	13.23%	MTX110
Gelesis, Inc.	5.88%	—	PLENITY®

\*The ownership percentages were calculated based on the shares issued by the overseas R&D companies as at 30 June 2020

# The interest is held by Mr. Lam Kong through his privately-owned company

#### 5. Deployment and Development of Generics with Competitiveness

The Group pays great attention to complex generics with high technology barriers, to enhance the accessibility of drugs among patients. Meanwhile, capitalizing on the opportunity brought by the National Volume-based Procurement, the Group selectively deployed generic clusters with market competitiveness to pursue additional growth.

As at 30 June 2020, the Group owned exclusive licenses of one complex generic and ten generics with market competitiveness in Mainland China and/or HK SAR, Macau SAR and TWN. Among them, nine generics

including the complex generic have been approved for marketing in the U.S. or Europe. The therapeutic fields of the Group’s generic portfolio included nervous system, immune system, orthopedics, digestive system, psychiatry, oncology, etc. According to 2019 IQVIA data, the total sales of drugs with the same active pharmaceutical ingredients (“API”) of the above complex generic and generics in Mainland China were more than USD1.8 billion.

During the Reporting Period, the Group actively worked on registration of the complex generic and generics in China. As at 30 June 2020, the status of the registration progress is as follows:

<b>Product</b>	<b>Indication</b>	<b>Registration Progress in China</b>	<b>2019 IQVIA Data of Products with the Same API</b>
Tacrolimus Capsules	Liver or kidney transplant rejection	ANDA Accepted	~RMB3.3 billion
Etoricoxib Tablets	Osteoarthritis, acute gouty arthritis, primary dysmenorrhea	ANDA Accepted	~RMB0.4 billion
Tetrabenazine Tablets	Huntington’s disease	Clinical Trial Application Approved	No Relevant Data

## **II. Existing Product Development**

### **1. Main Products**

#### ***Cardio-cerebrovascular Line***

The Group’s products under cardio-cerebrovascular line mainly include Plendil, XinHuoSu and Deanxit. During the Reporting Period, the products under cardio-cerebrovascular line recorded a revenue of RMB1,452.2 million, an increase of 8.3% compared with the same period last year. If excluding the effect of the “two-invoice system”, the revenue of products under cardio-cerebrovascular line would increase by 4.4% to RMB2,026.6 million compared with the same period last year, accounting for 57.0% of the Group’s revenue excluding the effect of the “two-invoice system”.

#### **Plendil (Felodipine Sustained Release Tablets)**

The Group owns the 20-year exclusive license for commercialization of Plendil in Mainland China. Manufactured by AstraZeneca Pharmaceutical Co., Ltd. (阿斯利康製藥有限公司), Plendil is used to treat hypertension and stable angina pectoris and is included in the NRDL and the National Essential Drugs List

(“NEDL”). Felodipine was recommended by the *2018 Revised Edition of Chinese Guidelines for Prevention and Treatment of Hypertension* and the *2019 Chinese Guidelines for the Hypertension Management in the Elderly*. During the Reporting Period, the Group strengthened the academic promotion and steadily promoted the expansion of and penetration in the lower-tier hospitals in county-level market and community medical institutions while focusing on the core market. By means such as the care for chronic diseases, the Group promoted the carrying capacity of the retail network and further enhanced the brand image and market recognition of Plendil. Meanwhile, the policy in extending the prescription period for chronic diseases during the epidemic period contributed to the sound growth of the product.

#### **XinHuoSu (Recombinant Human Brain Natriuretic Peptide for Injection)**

XinHuoSu, manufactured by Chengdu Rhodiola Biological Pharmaceutical Co., Ltd., a subsidiary of Tibet Pharmaceutical (an associated company of the Group) in which the Group holds a 37.36% interest, is a National Class One biological agent used to treat acute heart failure, and also the only Recombinant Human Brain Natriuretic Peptide (“rhBNP”) currently available in China market. XinHuoSu is included in the NRDL and recommended by the first *Acute Heart Failure Diagnosis and Treatment Guideline (2010)* in China. rhBNP has been recommended by the *Guidelines for the Rational Medication of Heart Failure Second Edition (2019)* and the *Acute Heart Failure Emergency Diagnosis and Treatment Guideline (2019)*, and included in the *Expert Advice on Diagnosis and Treatment of Combined Cardiac Insufficiency of COVID-19* during the Reporting Period. It has gradually become a representative drug in the field of acute heart failure. During the Reporting Period, the Group deepened its work in the field of cardiology and pushed forward the expert network construction and academic platform integration in the field of critical and emergency conditions of cardiothoracic surgery, to strengthen the brand and academic influence of the product.

#### **Deanxit (Flupentixol and Melitracen Tablets)**

Deanxit, manufactured by H. Lundbeck A/S of Denmark, is used for the treatment of mild-to-moderate depression, anxiety and psychosomatic affections, and is in the NRDL. Based on IQVIA data in 2019, Deanxit ranked first in the market share of antidepressant drugs in China. Flupentixol and Melitracen has been recommended by the *Guidelines for the Diagnosis and Treatment of Common Diseases of the Nervous System with Depression*. During the Reporting Period, the Group constantly reinforced the academic promotion in key departments such as neurology, gastroenterology and cardiology, deepening doctors’ and patients’ cognition and understanding of the academic value of Deanxit. The Group also actively expedited retail network construction and increased retail traffic by organizing public lectures, etc. to boost the further increase of market share.

According to the extension mechanism under the addendum signed on 31 January 2013 with Lundbeck Export A/S for its product Deanxit, during the Reporting Period, the Group’s (acting through its wholly-owned

subsidiary) exclusive promotion and sales right of Deanxit in Mainland China has been extended from 31 December 2020 to 31 December 2022.

### ***Digestion Line***

The Group's products under digestion line mainly include Ursofalk, Salofalk, Bioflor and Combizym. During the Reporting Period, the revenue of products under digestion line increased by 12.7% to RMB1,157.9 million compared with the same period last year, accounting for 32.6% of the Group's revenue excluding the effect of the "two-invoice system".

### **Ursofalk (Ursodeoxycholic Acid Capsules)**

Ursofalk is manufactured by Losan Pharma GmbH, Germany, the entrusted manufacturer of Dr. Falk Pharma GmbH ("Falk"), Germany. Listed in the NRDL, Ursofalk is used for the treatment of cholesterol gallstones in the gallbladder, cholestatic liver disease and biliary reflux gastritis. Based on IQVIA data in 2019, Ursofalk was the best-selling ursodeoxycholic acid drug in China and stably ranked first in sales among products in the Chinese cholagogue market. Ursodeoxycholic has been recommended by the *Diagnosis and Management of Autoimmune Hepatitis in Adults and Children: 2019 Practice Guidance and Guidelines from the American Association for the Study of Liver Diseases* and the *Chinese Consensus on the Diagnosis and Treatment of Liver Fibrosis 2019*. During the Reporting Period, focusing on the core therapeutic areas, the Group built advanced academic platforms to deepen the brand image vertically. At the same time, adhering to the differentiation promotion strategy, the Group carried out multi-level academic activities in different academic directions to explore new growth points for the product.

### **Salofalk (Mesalazine)**

Salofalk suppositories and enemas are manufactured by Vifor AG Zweigniederlassung Medicin Etingen, Switzerland, and the enteric-coated tablets of Salofalk are manufactured by Losan Pharma GmbH, Germany. Both are the entrusted manufacturers of Falk, Germany. Salofalk is mainly used to treat ulcerative colitis, including the treatment of acute exacerbations and the maintenance treatment to prevent recurrence, as well as the treatment of acute exacerbations of Crohn's disease. Salofalk is included in the NRDL and the NEDL, and is the Mesalazine with the fullest dosage forms in China market currently. Based on IQVIA data in 2019, Salofalk ranked first in the market share of inflammatory bowel disorder drugs in China. Mesalazine has been recommended by the *2019 British Society of Gastroenterology Consensus Guidelines on the Management of Inflammatory Bowel Disease in Adults* and the *Expert Consensus on Management of Inflammatory Bowel Disease During Pregnancy (2019)*, and during the Reporting Period, it was included in the *Expert Advice on Management of Patients with Inflammatory Bowel Disease during Epidemic of 2019 Novel Coronavirus Pneumonia*. During the Reporting Period, the Group enhanced the academic promotion through multiple channels, actively elevated the level of diagnosis, identification and standardized treatment of inflammatory

bowel disease, continuously improving the product influence. Meanwhile, the Group strengthened the retail supply management to ensure a stable supply and further expand the market share.

#### **Bioflor (*Saccharomyces Boulardii* Sachets)**

Bioflor, manufactured by Biocodex of France, is a probiotic agent used to treat diarrhea in adults and children, as well as diarrhea symptoms induced by intestinal flora disturbance. Bioflor is the global leading probiotics preparations currently. The latest published *Chinese Clinical Practice Guidelines for Children with Acute Infectious Diarrhea* and the *Probiotics and Prebiotics Guideline* updated by the World Gastroenterology Organization (“WGO”) have given Bioflor authoritative recommendations. During the Reporting Period, the Group continued to solidify the academic strengths in core clinical application fields, and concentrated on the promotion of differentiation advantages in “acute diarrhea” and “prevention of antibiotic-related diarrhea”. In the meantime, the Group, capitalizing on the product’s characteristics, actively expanded retail channels and conducted various novel promotional activities to improve the retail terminal sales.

#### **Combizym (*Oryz-Aspergillus Enzyme and Pancreatin Tablets*)**

The Group owns related assets of Combizym for Mainland China, HK SAR, Macau SAR, TWN, and other designated countries or areas, and has entrusted the manufacture of the product to Nordmark Arzneimittel GmbH & Co. KG, Germany. The main ingredients of Combizym are extracts of pancreatin and aspergillus oryzae enzymes. The product is used for treating dyspepsia caused by a decrease in digestive enzymes and is in the NRDL. Issued in 2019, the *Consensus on Diagnosis and Treatment of Chronic Cholecystitis and Gallstones in China (2018)* granted Combizym the recommendation for its relevant indications. During the Reporting Period, the Group organized highly frequent academic conferences and strengthened the concept of Combizym as a replacement therapy of pancreatic exocrine insufficiency. The Group also actively promoted the application of the product in senile dyspepsia and chemical dyspepsia in hepatobiliary diseases, etc., effectively driving the growth of the product.

#### **Ophthalmology Line**

The Group’s main product under ophthalmology line is Augentropfen Stulln Mono Eye Drops. During the Reporting Period, the revenue of the product under ophthalmology line decreased by 1.2% to RMB113.8 million, compared with the same period last year, accounting for 3.2% of the Group’s revenue excluding the effect of the “two-invoice system”.

#### **Augentropfen Stulln Mono Eye Drops (*Esculin and Digitalisglycosides Eye Drops*)**

The Group owns related assets of Augentropfen Stulln Mono Eye Drops for Mainland China, HK SAR, and Macau SAR, and has entrusted the manufacture to Pharma Stulln GmbH of Germany. Augentropfen Stulln Mono Eye Drops is used to treat senile macula degeneration and all forms of asthenopia. It is the only eye

drops in China market for the treatment of macula degeneration, and it is the representative drug for the treatment of asthenopia. The product is preservative-free. As the therapeutic drug of asthenopia, Stulln was recommended by the *Expert Consensus on Perioperative Medication for Corneal Laser Refractive Surgery in China (2019)*. During the Reporting Period, the Group constantly deepened and refined the academic promotion in the subdivided field of asthenopia, and continuously consolidated the product application in the field of fundus diseases, improving the academic image of the product. At the same time, the Group strengthened the deployment of retail channels, to create a bigger market for the product.

### ***Dermatology Line***

The Group's products under dermatology line mainly include Hirudoid. During the Reporting Period, the revenue of products under dermatology line decreased by 0.9% to RMB85.2 million compared with the same period last year, accounting for 2.4% of the Group's revenue excluding the effect of the "two-invoice system".

### ***Hirudoid (Mucopolysaccharide Polysulfate Cream)***

The Group owns the related assets of Hirudoid for Mainland China, and has entrusted the manufacture of the product to Mobilat Produktions GmbH, Germany. Included in the NRDL, Hirudoid is used for the treatment of blunt traumata with or without hematomas, and superficial phlebitis that cannot be treated by compression. Mucopolysaccharide polysulfate was recommended by the *Japan JSA Guidelines for Atopic Dermatitis* and China's first edition of *Expert Consensus on Diagnosis and Treatment of Senile Skin Pruritus* successively. During the Reporting Period, it was recommended by the *Suggestions for Medical Staff on Intravenous Infusion Treatment for Patients with COVID-19* issued by Chinese Nursing Association, the *Chinese Expert Consensus on Prevention and Treatment Catheter-Related Venous Thrombosis (2020 edition)* published by Chinese Chapter of the International Union of Angiology and Peripheral Vascular Disease Chapter of Chinese Geriatrics Society, and the *Protection, Diagnosis and Treatment Standards of Dermatology Department in Period of COVID-19 Prevention and Control* issued by Dermatovenereology Branch of Chinese Medical Association. During the Reporting Period, deeply engaged in the field of skin treatment and leveraging the inclusion in the NRDL, the Group consolidated the position of Hirudoid as a conventional drug for thrombophlebitis, while continuously strengthening cooperation with third-party platforms in the retail sector to increase sales outside hospitals.

## **2. Other Products**

During the Reporting Period, other products sold and promoted by the Group recorded revenue of RMB299.0 million, a decrease of 24.3% compared with the same period last year. If excluding the effect of the "two-invoice system", the revenue would decrease by 25.4% to RMB173.5 million compared with the same period last year, accounting for 4.9% of the Group's revenue excluding the effect of the "two-invoice system".

### **III. Promotion System**

The professional, compliant and efficient promotion system is a strong carrier for the Group's products to attain long-term steady growth, and also an important cornerstone for innovative products to achieve successful commercialization in the future. During the Reporting Period, the Group focused on the expansion of the promotion network and strengthened the market segmentation as well as the lower-tier market penetration. The Group actively explored the improvement and innovation of the promotion model while solidifying the existing promotion system, so as to accumulate experiences and make deployments in advance for the academic promotion of innovative products. In the meantime, aiming to build a more professional and compliant promotion team with higher execution capability, the Group further enhanced the job qualification and employee training system, optimized the remuneration and incentive system, and intensified the compliance training and inspection. Firmly seizing the opportunities in the COVID-19 crisis, the Group capitalized on digital tools to hold online academic conferences with high frequency, and reinforced application of digitalization in multi-dimensions to improve the operation efficiency.

During the Reporting Period, the prescription outflow was intensified under the influence of COVID-19, the National Volume-based Procurement, and hierarchical diagnosis and treatment. The Group continued to promote the construction of the retail network, expanded the coverage of retail chains and terminal stores, and further strengthened the cooperation with e-commerce platforms.

During the Reporting Period, the Group's promotion network covered about 57,000 hospitals and medical institutions in China.

### **IV. Manufacturing Facilities**

As at 30 June 2020, the Group owned pharmaceutical manufacturing sites in Hunan, Hebei and Shenzhen, occupying a total area of more than 110,000 square meters. The Group has the Pharmaceutical Production License and the Pharmaceutical GMP Certificate for various dosage forms such as powder, oral solution, small-volume injections, tablets, hard capsules, etc. With more than two decades of pharmaceutical production experiences, the Group has instituted stringent quality management standards and regulations to guarantee the product quality, ensuring the localized preparation manufacturing of overseas innovative products in China.

### **Impacts of COVID-19**

In the first half of 2020, the raging COVID-19 epidemic severely affected social and economic activities as

well as people's lives. To fight against the epidemic, the government, medical workers, enterprises, and the generic public made efforts together to demonstrate love and responsibility with actions, making staged achievements in the epidemic prevention and control. Facing the epidemic, the Group responded quickly by purchasing protection and epidemic prevention materials globally and donating them to frontline departments and medical workers. Meanwhile, the Group donated cash promptly to Wuhan Charity Federation to jointly fight against the epidemic. During the Reporting Period, some of the Group's products were slightly affected negatively by the decline of hospital patient traffic. Despite this, benefiting from the brand advantages and the application of digital tools, the Group's net profit growth in the first half of 2020 was in line with expectation. The Group will continue to pay close attention to the development of the epidemic and the trend of epidemic prevention and control and take appropriate precautions to ensure steady progress in all work.

## **Future Development**

The Group focuses firmly on the two core values in the pharmaceutical industry chain – product competence and promotion capability. Capitalizing on its extensive global resources, the Group will continue to expand the innovative pipeline and facilitate the further development and commercialization of drugs in China, so as to enhance product competence. At the same time, the Group will continuously strengthen the professional, compliant and efficient promotion system to achieve sustainable and steady growth.

- ***Accelerating the Development and Commercialization of Innovative Drugs in China***

Fully leveraging its mature experience in registration and clinical practices in China, while integrating the resources of medical experts and principal investigators in a wide range of therapeutic fields, the Group will accelerate the progress of patient enrollment and strengthen project coordination and control to promote the process of the comparative PK study and the clinical trials for registration. Meanwhile, the Group will further expand the high-quality registration and clinical teams and accelerate the registration and clinical processes of innovative drugs, so as to commercialize the innovative products in China as soon as possible.

- ***Constantly Expanding the Innovative Pipeline to Fulfil the Clinical Needs in China***

The Group will further utilize its global resources and the good reputation it enjoys, alongside close monitoring of the cutting-edge international trends and based on the actual medical demands of Chinese patients, to continuously assess and deploy innovative products with differentiation competitive advantages and promising market potential at relatively high innovation level. These initiatives aim to ensure the Group's sustainable supplies of commercialized innovative products in China in the short, medium and long term.

- ***Maintaining Efficient Operation and Achieving Stable Growth of the Existing Products***

The Group will further explore and improve the evidence-based medical evidence, to increase the academic

influence, and solidify the competitive advantages and leading market positions of the existing products. Meanwhile, the Group will continue to expand and refine the academic promotion network, and maintain the professionalism and compliance of the academic promotion, while actively exploring innovation and enhancing the application of digitalization, to boost the continuous and steady growth of the existing products and pave the way for the future commercialization of innovative products in China.

Looking forward, adhering to the mission of “Offering competitive products and services to meet China’s unmet medical needs”, CMS will benefit and provide Chinese patients with more effective, safer, and more cost-effective drugs.

## **Financial Review**

### **Turnover**

Turnover increased by 4.8% from RMB2,964.4 million for the six months ended 30 June 2019 to RMB3,108.1 million for the six months ended 30 June 2020; excluding the effect of the “two-invoice system”, turnover increased by 4.6% to RMB3,557.1 million for the six months ended 30 June 2020 from RMB3,401.5 million for the six months ended 30 June 2019, mainly due to an increase in sales volume.

### **Gross Profit and Gross Profit Margin**

Gross profit increased by 3.4% from RMB2,217.5 million for the six months ended 30 June 2019 to RMB2,293.4 million for the six months ended 30 June 2020; excluding the effect of the “two-invoice system”, gross profit increased by 6.8% from RMB2,023.2 million for the six months ended 30 June 2019 to RMB2,161.7 million for the six months ended 30 June 2020, primarily reflecting growth in turnover. For the six months ended 30 June 2020, gross profit margin was 73.8%, representing a decrease of 1.0 percentage point from 74.8% for the six months ended 30 June 2019; excluding the effect of the “two-invoice system”, gross profit margin increased by 1.3 percentage points to 60.8% for the six months ended 30 June 2020 from 59.5% for the six months ended 30 June 2019, mainly due to a change in the sales weight of products.

### **Selling Expenses**

Selling expenses decreased by 6.3% from RMB881.4 million for the six months ended 30 June 2019 to RMB825.6 million for the six months ended 30 June 2020. Selling expenses as a percentage of turnover was 26.6% for the six months ended 30 June 2020, representing a decrease of 3.1 percentage points from 29.7% for the six months ended 30 June 2019. Excluding the effect of the “two-invoice system”, selling expenses as a percentage of turnover decreased by 0.7 percentage point to 19.5% for the six months ended 30 June 2020 from 20.2% for the six months ended 30 June 2019, mainly due to a decrease in academic promotion activities through offline model during the outbreak of epidemic disease.

### **Administrative Expenses**

Administrative expenses increased by 2.6% from RMB96.5 million for the six months ended 30 June 2019 to RMB99.0 million for the six months ended 30 June 2020. Administrative expenses as a percentage of turnover for the six months ended 30 June 2020 was 3.2%, representing a decrease of 0.1 percentage point from 3.3% for the six months ended 30 June 2019. Excluding the effect of the “two-invoice system”, administrative expenses as a percentage of turnover for the six months ended 30 June 2020 was 2.8%, same as that for the six months ended 30 June 2019, mainly due to the benefit from economies of scale.

### **Research and Development Expenditures**

The Group’s research and development expenditures included investments for the continuous expansion of product pipelines, expenditures on development, clinical trial and registration of new products, salaries and related expenses of staff who were engaged in the aforesaid affairs. Research and development expenditures included the expensed research and development expenditures (i.e. research and development expenses) and the capitalized research and development expenditures.

Total research and development expenditures increased by 138.6% from RMB153.3 million for the six months ended 30 June 2019 to RMB365.7 million for the six months ended 30 June 2020. Total research and development expenditures as a percentage of turnover for the six months ended 30 June 2020 was 11.8%, representing an increase of 6.6 percentage points from 5.2% for the six months ended 30 June 2019. Excluding the effect of the “two-invoice system”, total research and development expenditures as a percentage of turnover increased by 5.8 percentage points to 10.3% for the six months ended 30 June 2020 from 4.5% for the six months ended 30 June 2019, primarily reflecting an expansion of product pipelines and an increase in research and development activities.

Research and development expenses increased by 96.6% from RMB15.4 million for the six months ended 30 June 2019 to RMB30.4 million for the six months ended 30 June 2020. Research and development expenses as a percentage of turnover for the six months ended 30 June 2020 was 1.0%, representing an increase of 0.5 percentage point from 0.5% for the six months ended 30 June 2019. Excluding the effect of the “two-invoice system”, research and development expenses as a percentage of turnover increased by 0.4 percentage point to 0.9% for the six months ended 30 June 2020 from 0.5% for the six months ended 30 June 2019.

Capitalized research and development expenditures (set out in the table below) increased by 143.3% from RMB137.8 million for the six months ended 30 June 2019 to RMB335.3 million for the six months ended 30 June 2020. Capitalized research and development expenditures as a percentage of turnover for the six months ended 30 June 2020 was 10.8%, representing an increase of 6.2 percentage points from 4.6% for the six months

ended 30 June 2019. Excluding the effect of the “two-invoice system”, capitalized research and development expenditures as a percentage of turnover increased by 5.3 percentage points to 9.4% for the six months ended 30 June 2020 from 4.1% for the six months ended 30 June 2019.

	<u>Six months ended 30 June</u>	
	<u>2020</u>	<u>2019</u>
	RMB'000	RMB'000
Payment for acquisition of equity investments		
in research and development companies	142,632	34,705
Payment for acquisition of product rights	192,711	103,121
	<u>335,343</u>	<u>137,826</u>

#### **Other Gains and Losses**

Other gains and losses increased by 35.6% from a gain of RMB46.7 million for the six months ended 30 June 2019 to a gain of RMB63.3 million for the six months ended 30 June 2020, mainly due to increases in interest income and government subsidies.

#### **Share of Result of Associates**

Share of result of associates increased by 42.6% from RMB56.8 million for the six months ended 30 June 2019 to RMB81.0 million for the six months ended 30 June 2020, mainly reflecting an increase in profit of the associate Tibet Pharmaceutical.

#### **Finance Costs**

Finance costs decreased by 47.2% from RMB29.1 million for the six months ended 30 June 2019 to RMB15.3 million for the six months ended 30 June 2020, mainly due to decreases in amount and interest rate of loans.

#### **Income Tax Expense**

Income tax expense increased by 27.4% from RMB131.0 million for the six months ended 30 June 2019 to RMB166.9 million for the six months ended 30 June 2020, primarily reflecting an increase in profit and the effect on the internal reorganization of the Group in 2019.

As disclosed in the Company’s annual report 2019, the applicable income tax rate (3% or 24%) of the Group’s former subsidiary CMS Pharma Co., Ltd for the year ended 31 December 2019 is still to be approved by the Malaysia government. As at the date that the condensed consolidated financial statements were approved for

issue, pursuant to the circular on extension of income tax filing issued by the Malaysia tax authority, CMS Pharma Co., Ltd has not yet completed its income tax filing and payment for the year ended 31 December 2019, therefore the related income tax provision remained.

### **Profit for the Period**

Profit for the period increased by 11.4% from RMB1,167.5 million for the six months ended 30 June 2019 to RMB1,300.5 million for the six months ended 30 June 2020, mainly due to the continuous growth in turnover, the decreases in academic promotion activities through offline model, and the benefit from economies of scale.

### **Inventories**

Inventories increased by 5.7% from RMB407.1 million as at 31 December 2019 to RMB430.3 million as at 30 June 2020. Average inventory turnover days decreased by 12 days from 106 days for the six months ended 30 June 2019 to 94 days for the six months ended 30 June 2020, primarily reflecting the improvement on management of inventories.

### **Trade Receivables**

Trade receivables decreased by 7.4% from RMB1,001.9 million as at 31 December 2019 to RMB928.1 million as at 30 June 2020. Average trade receivables turnover days decreased by 17 days from 74 days for the six months ended 30 June 2019 to 57 days for the six months ended 30 June 2020, primarily reflecting the improvement on management of trade receivables.

### **Trade Payables**

Trade payables increased by 84.8% from RMB44.0 million as at 31 December 2019 to RMB81.4 million as at 30 June 2020. Average trade payables days decreased by 13 days from 27 days for the six months ended 30 June 2019 to 14 days for the six months ended 30 June 2020, primarily reflecting the difference in time points of inventory purchases.

### **Liquidity, Financial Resources, Capital Structure and Gearing Ratio**

As at 30 June 2020, the Group's bank balances and cash amounted to RMB2,109.1 million while readily realizable bank acceptance bills amounted to RMB315.6 million. As at 31 December 2019, our bank balances and cash amounted to RMB1,365.0 million while readily realizable bank acceptance bills amounted to RMB414.0 million.

The Group had bank borrowings of RMB686.0 million as at 30 June 2020 (31 December 2019: RMB693.9 million). During the period ended 30 June 2020, the Group's bank loans decreased by a net amount of RMB7.9 million, mainly due to repayment of part of loans. The weighted average interest rate of loans was 3.7% per

annum. Except for loans amounting to RMB48.8 million which were due within one year and classified as current liabilities accordingly, all the remaining loans were due over one year and then classified as non-current liabilities.

As at 30 June 2020 and 31 December 2019, the Group had a gearing ratio (being the bank borrowings of the Group divided by the total assets of the Group) of approximately 5.7% and 6.2%, respectively.

The Group's liquidity requirements will be satisfied by a combination of cash flow generated from operating activities, bank loans and other financing means which the Company may from time to time consider appropriate.

### **Exposure to Fluctuations in Exchange Rates and Interest Rates**

The Group is mainly exposed to currency risk of the US\$, EUR, GBP, CHF and HK\$. The conversion of RMB into foreign currencies is subject to the rules and regulations of foreign exchange control promulgated by the PRC government. Any significant exchange rate fluctuations of foreign currencies against RMB may have a financial impact on the Group. The Group closely monitors the fluctuation of exchange rates and reviews the foreign currency risk management strategy from time to time, and the management will consider hedging foreign currency exposure as appropriate. As at 30 June 2020, the Group has entered into certain foreign exchange forward contracts to hedge the foreign currency risk.

The Group will closely monitor the interest rate movements so as to mitigate the expected interest rate risk.

### **Pledge of Assets**

As at 30 June 2020, the Group has pledged property, plant and equipment and leasehold land with net book values of approximately RMB68,924,000 and RMB15,705,000 respectively to secure general banking facilities granted to the Group.

### **Contingent Liabilities**

As at 30 June 2020, the Group had no material contingent liabilities.

### **Loan Agreements with Covenants Relating to Specific Performance of the Controlling Shareholder**

(i)

On 20 June 2017, Sky United Trading Limited, a wholly-owned subsidiary of the Company (as borrower, the "Borrower") and the Company (as guarantor) entered into a facility agreement (the "Facility Agreement") with Standard Chartered Bank (Hong Kong) Limited (as original lender, mandated lead arranger and bookrunner and agent) in respect of a US\$300,000,000 term loan facility (the "Facility") made available to the Borrower

for a term of 36 months from the first utilization date under the Facility Agreement.

Pursuant to the Facility Agreement, if, among other things, Mr. Lam Kong, the chairman of the Board, an executive Director and a controlling shareholder (as defined in the Listing Rules of SEHK) of the Company: (i) ceases to directly or indirectly own more than 30% of the total issued shares (of each class) in the Company; or (ii) ceases to directly or indirectly be the single largest shareholder in the issued shares (of each class) in the Company, the agent (acting on the instructions of the majority lenders under the Facility) may, by not less than 30 days' notice in advance to the Borrower, cancel all commitments under the Facility and declare that all outstanding loans together with accrued interest and all other amounts accrued under the Facility will become immediately due and payable. As at 30 June 2020, Mr. Lam Kong (directly and indirectly) holds approximately 45.12% of the total issued ordinary share capital of the Company.

The loan under the Facility was paid off during the Reporting Period.

(ii)

On 26 March 2020, Sky United Trading Limited, a wholly-owned subsidiary of the Company (as borrower, the "Borrower") and the Company (as guarantor) entered into a facility agreement (the "Facility Agreement") with DBS Bank (China) Limited (as lender) in respect of a US\$50,000,000 term loan facility (the "Facility") made available to the Borrower for a term of 36 months from the first utilization date under the Facility Agreement. On 27 March 2020, Sky United Trading Limited, a wholly-owned subsidiary of the Company (as borrower, the "Borrower") and the Company (as guarantor) entered into a facility agreement (the "Facility Agreement") with Standard Chartered Bank (Hong Kong) Limited (as lender) in respect of a US\$40,000,000 term loan facility (the "Facility") made available to the Borrower for a term of 36 months from the first utilization date under the Facility Agreement.

Pursuant to the Facility Agreement, if, among other things, Mr. Lam Kong, the chairman of the Board, an executive Director and a controlling shareholder (as defined in the Listing Rules of SEHK) of the Company: (i) ceases to directly or indirectly own more than 30% of the total issued shares (of each class) in the Company; or (ii) ceases to directly or indirectly be the single largest shareholder in the issued shares (of each class) in the Company, the lender may, by not less than 30 days' notice in advance to the Borrower, cancel all commitments under the Facility and declare that all outstanding loans together with accrued interest and all other amounts accrued under the Facility will become immediately due and payable. As at 30 June 2020, Mr. Lam Kong (directly and indirectly) holds approximately 45.12% of the total issued ordinary share capital of the Company.

## Other Information

### Interim Dividend

The Board has resolved to pay an interim dividend of RMB0.2105 (equivalent to HK\$0.234) per ordinary share of the Company for the six months ended 30 June 2020 to the shareholders whose names appear on the register of members of the Company on Friday, 28 August 2020 (the “Record Date”). Payment of such interim dividend is expected to be made to the shareholders on about Friday, 4 September 2020.

### Closure of Register of Members

The register of members of the Company will be closed on Friday, 28 August 2020, on which the registration of transfer of shares of the Company (“Shares”) will be suspended. To qualify for the interim dividend, all transfer forms of Shares accompanied by the relevant share certificates must be lodged with the Company’s branch share registrar in Hong Kong, Computershare Hong Kong Investor Services Limited, at Shops 1712-1716, 17th Floor, Hopewell Centre, 183 Queen’s Road East, Wanchai, Hong Kong, for registration no later than 4:30 p.m. on Thursday, 27 August 2020.

### Purchase, Sale or Redemption of the Company’s Listed Securities

For the six months ended 30 June 2020, the Company repurchased an aggregate of 9,648,000 ordinary shares with a nominal value of US \$0.005 each on the SEHK at an aggregate consideration of HK\$98,164,100. All of the purchased shares were cancelled on 30 March 2020. The Board believes that given the current financial resources of the Company, the share repurchase would not affect the Company’s solid financial position in any material respect, and it would lead to an enhancement of the net asset value per share and/or earnings per share, which is in the interest of the shareholders as a whole.

Details of the repurchase are as follows:

Month of Repurchase	Number of Shares Repurchased	Price per Share (HK\$)		Aggregate Consideration Paid (HK\$)
		Highest Price	Lowest Price	
February 2020	9,648,000	10.30	10.04	98,164,100
Total	9,648,000	-	-	98,164,100

Save as disclosed above, none of the Company or any of its subsidiaries has purchased, sold or redeemed any of the listed securities of the Company during the Reporting Period.

### Audit Committee

The Company established an Audit Committee in 2007. The Audit Committee currently comprises three independent non-executive Directors, and is chaired by Mr. Wu Chi Keung, with Mr. Leung Chong Shun and Ms. Luo, Laura Ying as Committee members. Mr. Cheung Kam Shing, Terry resigned as an independent non-executive Director as well as a member of the Audit Committee of the Company on 31 March 2020, and Ms. Luo, Laura Ying was appointed as an independent non-executive Director as well as a member of the Audit Committee of the Company on 31 March 2020.

The primary duties of the Audit Committee are to provide the Directors with an independent review of the effectiveness of the financial reporting process, internal control and risk management system of the Company, to oversee the audit process and to perform other duties and responsibilities as assigned by the Directors. The Audit Committee also oversees the Company's appointment of external auditors.

The Company's interim result announcement and interim report for the six months ended 30 June 2020 have been reviewed by the Audit Committee of the Company.

## **Corporate Governance Practices**

During the Reporting Period, the Company has complied with the applicable principles and code provisions of the applicable Corporate Governance Code (the "CG Code") as set out in Appendix 14 to the Listing Rules, except for a deviation from the Code Provision A.2.1 in respect of the roles of Chairman and Chief Executive which shall not be performed by the same individual.

Mr. Lam Kong has been both the Chairman and Chief Executive of the Company and his responsibilities are clearly set out in writing and approved by the Board. Given the Group's current stage of development, the Board considers that vesting the roles of Chairman and Chief Executive in the same person facilitates the execution of the Group's business strategies and maximizes the effectiveness of its operations. The Board shall nevertheless review the structure from time to time and shall consider any appropriate adjustments should new circumstances arise.

The Company makes available to the Directors monthly updates, in order to keep the Directors informed of the Company's performance and operations. In addition, the Directors also receive regular updates from time to time on changes and developments in the legislation and regulatory environments which apply to the Company's business.

All Directors participate in continuous professional development to develop and refresh their knowledge and skills and to ensure that their contribution to the Board remains informed and relevant. The Company keeps records of the training received by Directors.

## **Directors' Securities Transactions**

The Company adopted the Model Code for Securities Transactions by Directors of Listed Issuers (amended from time to time) (the "Model Code") as set out in Appendix 10 of the Listing Rules as the code of conduct for Directors' securities transactions. Having made specific inquiries in relation to the compliance with the Model Code for securities transactions by Directors, the Company confirmed that all the Directors have complied with the relevant standards for securities transactions by Directors set out in the Model Code during the Reporting Period. The Model Code also applies to other specified senior management of the Company.

Employees who are likely to be in possession of unpublished price-sensitive information about the Company are also subject to compliance with guidelines on no less exacting terms than the Model Code. No incident of non-compliance with the guidelines by such employees was noted by the Company during the Reporting Period.

## **Disclosure of Information**

The information provided in this announcement is only the summary of 2020 Interim Report of the Company. The 2020 Interim Report will be duly dispatched to shareholders of the Company and published on the websites of the SEHK ([www.hkexnews.hk](http://www.hkexnews.hk)) and the Company ([www.cms.net.cn](http://www.cms.net.cn)).

By order of the Board  
China Medical System Holdings Limited  
*Chairman*  
**Lam Kong**

Hong Kong, 12 August 2020

*As at the date of the announcement, the Directors of the Company comprise (i) Mr. Lam Kong, Mr. Chen Hongbing and Ms. Chen Yanling as executive Directors; and (ii) Mr. Wu Chi Keung, Mr. Leung Chong Shun and Ms. Luo, Laura Ying as independent non-executive Directors.*